

Appl. No. 10/036,418
Atty. Docket No. 9056#LS
Amdt. Dated 22 March 2005
Reply to Office Action of 29 December 2004
Customer No. 27752

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 1. (Currently amended) A method for assaying islet neogenesis associated protein (INGAP) molecule in a test sample, comprising:

- a. contacting a solid support comprising ~~bound~~ ^{bound} pre-attached antibodies with a test sample, wherein the antibodies specifically bind to an amino acid sequence FLSWVEGEESQKKLPSSRITC (SEQ ID NO: 1) of INGAP molecule protein, whereby INGAP protein molecule in the test sample binds to the antibodies and thereby to the solid support;
- b. removing the test sample which has not bound to the antibodies and thereby not bound to the solid support;
- c. contacting the solid support with a quantity of a labeled INGAP molecule, whereby all or a portion of the quantity of labeled INGAP molecule binds to the antibodies and thereby to the solid support;
- d. removing labeled INGAP molecule which has not bound to the antibodies and thereby not bound to the solid support; and
- e. determining the amount of labeled INGAP molecule bound to the solid support wherein the amount of labeled INGAP molecule bound to the antibodies and thereby to the solid support is inversely related to the amount of INGAP protein molecule in the test sample.

Claim 2. (Currently amended) The method of claim 1 further comprising:

- a. generating a standard curve using a series of control samples having known quantities of labeled INGAP molecule; and
- b. comparing the amount of ~~marker protein~~ labeled INGAP molecule bound to the antibodies and thereby to the solid support with in presence of the test sample to the standard curve, whereby an the amount of INGAP molecule in the test sample is determined.

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Claim 3. (Currently amended) The method of claim 1 wherein the labeled INGAP molecule comprises a fusion protein comprising INGAP ~~protein~~ molecule and a marker protein.

Claim 4. (Original) The method of claim 3 wherein the marker protein is enzymatically active.

Claim 5. (Original) The method claim 3 wherein the marker protein is fluorescent.

Claim 6. (Currently amended) The method of claim 4 wherein a chromogenic substrate is contacted with the marker protein to determine the amount of marker protein bound to the solid support.

Claim 7. (Currently amended) The method of claim 1 wherein the labeled INGAP molecule ~~protein~~ is radioactively labeled.

Claim 8. (Currently amended) A method for assaying islet neogenesis associated protein (INGAP) molecule in a test sample, comprising: contacting

- a. antibodies which specifically bind to an amino acid sequence
FLSWVEGEESQKKLPSSRITC (SEQ ID NO: 1) of INGAP molecule
protein,
- b. a test sample which may contain INGAP molecule protein, and
- c. a labeled INGAP molecule; and

determining the amount of labeled INGAP molecule bound to the antibodies, wherein the amount of labeled INGAP molecule bound to the antibodies is inversely related to the amount of INGAP molecule protein in the test sample.

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Claim 9. (Currently amended) The method of claim 8 wherein the labeled INGAP molecule is a fusion protein comprising INGAP molecule ~~protein~~ and a marker protein.

Claim 10. (Currently amended) The method of claim 8 further comprising:

- a. generating a standard curve using a series of control samples having known quantities of INGAP molecule; and
- b. comparing the amount of ~~marker protein~~ labeled INGAP molecule bound to the solid support with in presence of the test sample to the standard curve, whereby an amount of INGAP molecule in the test sample is determined.

Claim 11. (Currently amended) The method of claim 8 wherein prior to the step of determining the amount of labeled INGAP molecule bound to the antibodies, the antibodies are separated from components which are not specifically bound to the antibodies.

Claim 12. (Original) The method of claim 9 wherein the marker protein is enzymatically active.

Claim 13. (Original) The method of claim 9 wherein the marker protein is fluorescent.

Claim 14. (Original) The method of claim 12 wherein a chromogenic substrate is contacted with the marker protein to determine the amount of marker protein bound to the antibodies.

Claims 15 - 23 (Canceled).

Claim 24. (Currently amended) A method for assaying islet neogenesis associated protein (INGAP) molecule in a test sample, comprising:

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- a. contacting a solid support comprising pre-attached bound antibodies with a test sample, wherein the antibodies specifically bind to an amino acid sequence selected from the group consisting of residues 104 – 118 (IGLHDP SHGTL PNGS; SEQ ID NO: 2), 139 – 152 (LAADRGYCAVLSQK; SEQ ID NO: 3), and 151 – 164 (QKSGFQKWRDFNCE; SEQ ID NO: 4) of INGAP molecule protein, whereby INGAP molecule protein in the test sample binds to the antibodies and thereby to the solid support;
- b. removing the test sample which has not bound to the antibodies and thereby not bound to the solid support;
- c. contacting the solid support with a quantity of a labeled INGAP molecule, whereby all or a portion of the quantity of labeled INGAP molecule binds to the antibodies and thereby to the solid support;
- d. removing labeled INGAP molecule which has not bound to the antibodies and thereby not bound to the solid support; and
- e. determining the amount of labeled INGAP molecule bound to the antibodies and thereby to the solid support wherein the amount of labeled INGAP molecule bound to the solid support is inversely related to the amount of INGAP protein molecule in the test sample.

Claim 25. (Currently amended) The method of claim 24 further comprising:

- a. generating a standard curve using a series of control samples having known quantities of labeled INGAP molecule; and
- b. comparing the amount of ~~marker protein~~ labeled INGAP molecule bound to the antibodies and thereby to the solid support with in presence of the test sample to the standard curve, whereby an the amount of INGAP molecule in the test sample is determined.

Claim 26. (Currently amended) The method of claim 24 wherein the labeled INGAP molecule comprises a fusion protein comprising INGAP molecule protein and a marker protein.

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Claim 27. (Original) The method of claim 26 wherein the marker protein is enzymatically active.

Claim 28. (Original) The method claim 26 wherein the marker protein is fluorescent.

Claim 29. (Currently amended) The method of claim 27 wherein a chromogenic substrate is contacted with the marker protein to determine the amount of marker protein bound to the solid support.

Claim 30. (Currently amended) The method of claim 24 wherein the labeled INGAP molecule protein is radioactively labeled.

Claim 31. (Currently amended) A method for assaying islet neogenesis associated protein (INGAP) molecule in a test sample, comprising: contacting

- a. antibodies which specifically bind to an amino acid sequence selected from the group consisting of residues 104 – 118 (IGLHDPSHGTLPNGS; SEQ ID NO: 2), 139 – 152 (LAADRGYCAVLSQK; SEQ ID NO: 3), and 151 – 164 (QKSGFQKWRDFNCE; SEQ ID NO: 4) of INGAP molecule protein,
- b. a test sample which may contain INGAP molecule protein, and
- c. a labeled INGAP molecule; and

determining the amount of labeled INGAP molecule bound to the antibodies, wherein the amount of labeled INGAP molecule bound to the antibodies is inversely related to the amount of INGAP molecule protein in the test sample.

Claim 32. (Currently amended) The method of claim 31 wherein the labeled INGAP molecule is a fusion protein comprising INGAP molecule protein and a marker protein.

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Claim 33. (Currently amended) The method of claim 31 further comprising:

- a. generating a standard curve using a series of control samples having known quantities of INGAP molecule; and
- b. comparing the amount of ~~marker protein~~ labeled INGAP molecule bound to the solid support ~~with~~ in presence of the test sample to the standard curve, whereby an amount of INGAP molecule in the test sample is determined.

Claim 34. (Currently amended) The method of claim 31 wherein prior to the step of determining the amount of labeled INGAP molecule bound to the antibodies, the antibodies are separated from components which are not specifically bound to the antibodies.

Claim 35. (Original) The method of claim 32 wherein the marker protein is enzymatically active.

Claim 36. (Original) The method of claim 32 wherein the marker protein is fluorescent.

Claim 37. (Original) The method of claim 36 wherein a chromogenic substrate is contacted with the marker protein to determine the amount of marker protein bound to the antibodies.

Claims 38 - 46 (Canceled).